510(k) SUMMARY

MAR 1 1 2013

Date: January 16, 2013

Applicant/Sponsor: Gold Standard Orthopaedics, LLC.
1226 Rowan St.
Louisville, KY 40203

Contact Person: David Baughman
President
David06@Baughmangroup.com
Phone (502) 581-8770

Proprietary Name: GSO GS1 Cannulated Screw System

Common Name: Spinal Implants

Classification Name: Spinal interlaminal fixation orthosis, 21 CFR 888.3050-KWP
Pedicle screw spinal system, 21 CFR 888.3070-MNH, MNI

Legally Marketed Devices to which Substantial Equivalence is claimed:

GSO GS1 Spinal System (K070966)
DePuy Spine VIPER System (K121020)
Medtronic Sofamor Danek CD Horizon Spinal System (K032265)

Device Description:

The GSO GS1 Spinal System consists of rods, screws, hooks, and connecting components that can be locked rigidly into various configurations to build a spinal construct specific to the needs of each individual patient. The implants are attached to the spine posteriorly by means of screws and/or hooks joined with rods.

The current submission, the GSO GS1 Cannulated Screw System, adds the following components to the GSO GS1 System: 5.5mm and ¼" straight longitudinal rods in lengths of 50 – 480mm; 5.5mm and ¼" pre-bent rods in lengths of 30 – 120mm; and multi-directional cannulated screws with standard or reduction heads in diameters of 5.5mm – 8.5 and lengths of 25mm – 100mm (depending on the screw diameter) to fit either 5.5mm or ¼" rods. These additional components are compatible with the previously cleared GSO GS1 rods, screws, hooks and connectors. The GSO GS1 Spinal System can be installed with any suitable instrumentation.

The GSO GS1 Spinal System components are manufactured from CP Titanium conforming to ASTM F67 and Ti-6Al-4V Titanium alloy conforming to ASTM F136.

Intended Use / Indications:

The GSO GS1 Cannulated Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. It is intended to be used as a temporary construct that assists normal healing and is not intended to replace normal body structures. The GSO GS1 Cannulated Screw System should be removed after fusion.

As a pedicle screw system, the GSO GS1 Cannulated Screw System is intended for patients: (a) having severe spondylolisthesis (Grade 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); (c) who are receiving fusions using autogenous bone graft only; and (d) who are having the device removed after the development of a solid fusion mass.

In addition, when used as a pedicle screw system, the GSO GS1 Cannulated Screw System is indicated for the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as a posterior, non-cervical, non-pedicle screw and/or hook fixation system, the GSO GS1 Cannulated Screw System is indicated for:

1. Degenerative disc disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
2. Idiopathic scoliosis
3. Kyphotic deformities of the spine
4. Paralytic scoliosis and/or pelvis obliquity
5. Vertebral fracture or dislocation
6. Neuromuscular scoliosis associated with pelvic obliquity
7. Vertebral fracture or dislocation
8. Tumors
9. Spondylolisthesis
10. Stenosis
11. Pseudarthrosis
12. Unsuccessful previous attempts at spinal fusion

For posterior, non-pedicle, screw use, the GSO GS1 screws are intended for sacral/iliac attachment only and the GSO GS1 hooks and crosslinks are intended for thoracic and/or lumbar use only.

Summary of Technologies/Substantial Equivalence:

The GSO GS1 Cannulated Screw System has the same indications, a similar design, and is manufactured from the same materials as the GSO GS1 Spinal System cleared in K070966. The cannulated screw components of the GSO GS1 Cannulated Screw System are similar in design to the cannulated screw components of the DePuy Spine VIPER System and the Medtronic Sofamor Danek CD Horizon Spinal System.

Non-Clinical Testing:

Testing of the GSO GS1 components was conducted according to ASTM F1717-12. This testing demonstrated that the failure loads for the GSO GS1 Cannulated Screw System were substantially equivalent to the failure loads for the predicate GSO GS1 Spinal System.

Clinical Testing:

Clinical testing was not necessary to demonstrate the substantial equivalence of the GSO GS1 Cannulated Screw System to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2013

Gold Standard Orthopaedics, LLC
% Mr. David Baughman
President
1226 Rowan Street
Louisville, Kentucky 40203

Re: K123487
Trade/Device Name: GSO GS1 Cannulated Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: January 18, 2013
Received: January 22, 2013

Dear Mr. Baughman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K123487

Device Name: GSO GS1 Cannulated Screw System

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Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123487

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